TESTIMONY ON BEHALF OF ADALTIS U.S. INC.

BY

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Before The

Committee on Government Reform
Subcommittee on Criminal Justice, Drug Policy and Human Resources
United States House of Representatives

Investigative Hearing:

The Conditions and Circumstances That Caused Inaccurate Test Results To Be Generated and Conveyed to Patients of Maryland General Hospital

May 18, 2004
Washington, D.C.

Chairman Souder, Congressman Cummings, and Members of the Criminal Justice, Drug Policy and Human Resources Subcommittee, my name is Richard Eckloff. On behalf of Adaltis U.S. Inc., thank you for your invitation to testify at this investigative hearing. As the company that sold and serviced the laboratory equipment on which the tests that are the subject of this hearing were performed, Adaltis U.S. appreciates this opportunity to assist the Subcommittee with its efforts to address the serious public health concerns raised by this matter.

From late 1994 until April 8th of this year, I was the General Manager of Adaltis U.S. Until late 1999, when its name was changed, the company was called Biochem Immunosystems U.S., Inc. On April 8th of this year, Adaltis U.S. sold all of its assets to Trinity Biotech.

Adaltis U.S. was, at all times relevant to your investigation, the domestic distributor for Adaltis Italia S.p.A., which manufactures automated processors. Adaltis U.S. also distributed diagnostic products manufactured by other companies. As General Manager, I was responsible for sales, marketing and product support for these products in the continental United States.

The equipment on which the tests at issue were performed is called a LABOTECH Automated Microplate Analyzer. The LABOTECH was cleared by the Food and Drug Administration ("FDA") as a Class II medical device in 1992. The LABOTECH is designed to robotically perform the processing steps that a medical technologist would manually perform to complete tests that are known as enzymatic immunoassays, or "EIAs."

The LABOTECH is an "open system." This means that it is programmable to perform tests utilizing test kits made by many different manufacturers. These test kits contain samples, called calibrators and controls, that are necessary to calibrate the analyzer to perform a particular manufacturer's test properly. Adaltis did *not* manufacture the HIV or hepatitis test kits that were used by Maryland General Hospital to perform the tests that are at issue here.

There are more than 2500 LABOTECHS currently in daily use at locations throughout the world. Of these, approximately 170 are currently in use in the United States, including LABOTECHS installed at prestigious medical institutions such as the National Institutes of Health in Bethesda, MD, Walter Reed Army Medical Center in Washington, D.C., and the Cleveland Clinic.

To our knowledge, invalid test results have not been generated by a LABOTECH and then reported to a patient by any hospital or laboratory other than Maryland General Hospital.

In the Subcommittee's letter of April 29, 2004, you advised us that you are seeking to understand the conditions and circumstances that caused inaccurate test results to be generated and conveyed to patients of Maryland General Hospital. Adaltis U.S. does not have access to much of the information that would be necessary to be responsive on this issue. Other members of this panel, as well as members of the two other panels that testified today, may be able to provide far more assistance to the Subcommittee. Nevertheless, Adaltis U.S. will share what it has learned.

We understand that the test results at issue were generated at the Maryland General Hospital between June 2002 and August 2003. We further understand that the test results were invalid because control readings were not within the ranges set by the test kit manufacturers. A review of our records indicates that, during this time period, there was a high number of service support requirements for this account. Nearly all of these support requirements were responsive to maintenance, training, and operator issues unrelated to failed runs due to test kit control readings. Our records indicate that only four calls were received from the Hospital due to such failed runs. Our records also indicate that all of these reported incidents were addressed by employing normal trouble shooting procedures and were satisfactorily resolved. Adaltis U.S.

was not aware that invalid test results were generated or that invalid test results were reported to patients. These facts first came to our attention when they were reported by the press in or about March of this year.

Shortly after Adaltis U.S. first learned about this matter, the FDA conducted an investigation at our headquarters in Allentown, Pennsylvania. The FDA did not tell us why it was conducting that investigation; however, the FDA did inform us that it was well aware of what had occurred at Maryland General Hospital. We have no further information about the FDA's investigation.

Adaltis U.S. has also learned that the Maryland Department of Health and Mental Hygiene has conducted an investigation of the invalid test results generated at Maryland General Hospital and that a report on that investigation has been prepared. We were not contacted by the Department in connection with its investigation. We have, however, followed the reports on the Department's investigation that have appeared in the press.

For example, in an Associated Press article published in the Washington Times on March 20, 2004, it was reported that: "[A]ccording to the state inspection report, lab personnel manipulated and eliminated readings showing completed blood tests might be inaccurate. The report said workers at all levels allowed results to be reported even when instrumentation and quality control materials were used improperly."[1/] Similarly, on March 23, 2004, the Associated Press reported that: "[A]ccording to a state inspection report, lab workers manipulated and

1/ F. Klug, *Lab Worker says thousands of HIV tests flawed,* Associated Press, March 20, 2004, published in *The Washington Times*.

eliminated machine readings showing that recently completed blood tests might be inaccurate and should be discarded."[2/]

Adaltis U.S. does not understand precisely what Maryland General Hospital workers were reportedly found to have done or how they generated the test results at issue. The press reports do make clear, however, that the LABOTECH properly indicated that the test results were invalid but that Maryland General Hospital personnel disregarded this information. Mr. Sabatini is here today to testify, and we certainly do not mean to speak for him. Nevertheless, we are aware that the Associated Press reported on March 12 of this year that: "State health secretary Nelson Sabatini said the problem appeared to be a personnel issue and *not* an equipment issue."[3/]

We are also aware that the College of American Pathologists, which is represented on this panel, issued a press release on May 11th stating that: "After thorough investigation, the College determined that what caused the errors appeared to have been deliberate data manipulation by laboratory employees. The employees edited the quality control reports of the testing instrument used."[4/]

Maryland General Hospital did finally make a report regarding the invalid test results on April 21st of this year—nine months after the last of the invalid test results was generated at the Hospital. At that time, the Hospital belatedly filed a MedWatch report with the FDA that asserts that LABOTECH malfunctions occurred resulting in invalid test results. That report, however,

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2/ W. Hall, *Hospital Moves To Correct Problem With Test Results,* Associated Press (March 23, 2004).

3/ A. Dominguez, *Maryland Hospital Urges HIV Retesting,* Associated Press (March 12, 2004)(emphasis added).

4/ College of American Pathologists, *Update on the Maryland General Hospital Laboratory Issue* (News Release, May 11, 2004).

provides no information about any specific incidents, gives no indication of the extent of the problem, and provides no information at all about the types of tests performed or the results obtained. Nevertheless, after we received a copy of the report form on April 26, 2004, we began an internal investigation. That investigation is still underway.

In sum, all information available to us at this time indicates that the circumstances that caused invalid test results to be generated and conveyed to patients of Maryland General Hospital were related to Hospital personnel and procedures—*not* to any malfunction of the LABOTECH. And we are unaware of any instances, other than those reported at Maryland General Hospital, where invalid test results have been generated by a LABOTECH and conveyed to patients.

Again, let me thank you for this opportunity to testify before you today. I would be happy to respond to questions you may have or to provide supplemental information you may request.